

Atty Dkt No: PP01468.103
USSN: 09/187,661
PATENT

Listing of Claims:

The following listing reflects amendments to the claims and replaces all prior versions and listings of claims in this application.

1. (Previously presented) A low salt-containing aqueous composition comprising biologically active human IGF-I or a biologically active variant thereof in a concentration of about 250 mg/ml or greater and a pH of pH 5.0 or greater, wherein said variant is a polypeptide that has at least 80% amino acid sequence identity to the amino acid sequence of human IGF-I.
2. (Canceled)
3. (Previously presented) The composition of claim 1, wherein said human IGF-I or variant thereof is present in a concentration of about 250 mg/ml to about 500 mg/ml.
4. (Previously amended) The composition of claim 1, wherein said human IGF-I or variant thereof is present in a concentration of about 350 mg/ml, and wherein said composition has a density of about 1.07 g/ml and a viscosity of about 15,700 cps.
- 5-12. (Canceled)
13. (Previously presented) A kit for reconstituting a pharmaceutical composition comprising biologically active human IGF-I or biologically active variant thereof, said kit comprising the composition of claim 1 and separately a pharmaceutically acceptable buffered solution having a pH less than or equal to pH 5.0.
- 14-15. (Canceled)
16. (Previously presented) A pharmaceutical composition comprising the composition of claim 1, and a pharmaceutically acceptable carrier.

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17. (Original) The pharmaceutical composition of claim 16, wherein said composition is a sustained-release formulation.

18. (Original) The pharmaceutical composition of claim 16, wherein said composition is a gel formulation.

19. (Previously presented) A cryogenically produced poly(D,L-lactide-co-glycolide) (PLGA) microsphere comprising the composition of claim 1.

20. (Previously presented) The microsphere of claim 19, wherein said microsphere comprises a lyophilized form of said composition.

21-27. (Canceled)

28. (Previously presented) The composition of claim 1, wherein said variant differs from the amino acid sequence for said human IGF-I by up to 5 amino acid residues.

29. (Previously presented) The composition of claim 1, wherein said variant differs from the amino acid sequence for said human IGF-I by up to 2 amino acid residues.

30. (Currently amended) The composition of claim 1, wherein said variant differs from the amino acid sequence for said human IGF-I by ~~four~~ one amino acid residue.

31. (Previously presented) The composition of claim 1, wherein said human IGF-I is recombinant human IGF-I.

32. (Currently amended) The composition of claim ~~1~~ 31, wherein said recombinant human IGF-I is present at a concentration of about 250 mg/ml to about 500 mg/ml.

33. (Currently amended) The composition of claim ~~1~~ 31, wherein said recombinant human IGF-I is present at a concentration of about 350 mg/ml, and wherein said composition has a density of about 1.07 g/ml and a viscosity of about 15,700 cps.

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34. (Previously presented) A low salt-containing aqueous composition comprising biologically active human IGF-I in a concentration of about 250 mg/ml or greater and a pH of pH 5.0 or greater.

35. (Previously presented) The composition of claim 34, wherein said human IGF-I is recombinant human IGF-I.

36. (Previously presented) The composition of claim 34, wherein said human IGF-I is present at a concentration of about 250 mg/ml to about 500 mg/ml.

37. (Previously presented) The composition of claim 34, wherein said human IGF-I is present at a concentration of about 350 mg/ml, and wherein said composition has a density of about 1.07 g/ml and a viscosity of about 15,700 cps.

38. (Previously presented) A pharmaceutical composition comprising the composition of claim 34, and a pharmaceutically acceptable carrier.

39. (Previously presented) A cryogenically produced poly(D,L-lactide-co-glycolide) (PLGA) microsphere comprising the composition of claim 34.

40. (Previously presented) A pharmaceutical composition comprising the composition of claim 37, and a pharmaceutically acceptable carrier.

41. (Previously presented) A cryogenically produced poly(D,L-lactide-co-glycolide) (PLGA) microsphere comprising the composition of claim 37.

42. (Previously presented) A low salt-containing aqueous composition comprising biologically active recombinant human IGF-I is a concentration of about 350 mg/ml, and wherein said composition has a density of about 1.07 g/ml and a viscosity of about 15,700 cps and a pH of pH 5.0 or greater.

43. (Previously presented) A pharmaceutical composition comprising the composition of claim 42, and a pharmaceutically acceptable carrier.

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44. (Currently amended) A cryogenically produced poly(D,L-lactide-co-glycolide) (PLGA) microsphere comprising the composition of claim 42.
45. (Previously presented) A pharmaceutical composition comprising the composition of claim 1, and a pharmaceutically acceptable excipient.
46. (Previously presented) The pharmaceutical composition of claim 45, wherein said composition is a sustained-release formulation.
47. (Previously presented) The pharmaceutical composition of claim 45, wherein said composition is a gel formulation.
48. (Previously presented) A pharmaceutical composition comprising the composition of claim 34, and a pharmaceutically acceptable excipient.
49. (Previously presented) A pharmaceutical composition comprising the composition of claim 37, and a pharmaceutically acceptable excipient.
50. (Previously presented) A pharmaceutical composition comprising the composition of claim 42, and a pharmaceutically acceptable excipient.